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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,042	06/01/2006	Tomislav Mihaljevic	BWY-005.01	1728
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FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			EXAMINER MARCETICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,042

Applicant(s)

MIHALJEVIC ET AL.

Examiner

Adam Marcetich

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-44 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 Jan 2006, 12 Jan 2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 3-15, 18-37 and 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al. (US Patent 5,702,368).

3. Regarding claims 1 and 24, Stevens discloses a method of cardioscopy and a cardioscopy apparatus comprising:

creating a primary heart bypass circuit for perfusing an organism (column 24, lines 17-21, column 25, lines 17-29, especially 25-29 and Fig. 16, withdrawing blood through inlets 218 and 219 and returning to patient through catheter 212 near external iliac artery);

creating a secondary circuit for perfusing the heart of the organism with a non-observation-impairing pumping medium (column 24, lines 22-26 and Fig. 16, aperture 221 for infusion of saline); and

observing the heart through the secondary circuit (column 25, lines 42-45 and Fig. 17, catheter 212 having instrumentation 237 including a cardioscope).

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4. Regarding claims 3, 12-15, 25 and 34-37, Stevens discloses perfusing with saline, an optically clear, oxygenatable, translucent and non-turbid substance (column 24, lines 17-21).
5. Regarding claims 4 and 26, Stevens discloses treating a patient (column 5, lines 11-15). A living patient is inherently perfused with blood.
6. Regarding claims 5 and 27, Stevens discloses a primary heart bypass circuit receiving blood from a vena cava and returning blood to the aorta (column 24, line 13; Fig. 16, venous catheter 211 within inferior vena cava 217 and column 24, lines 55-56; Fig. 16, aortic balloon catheter 212 within aortic root 226);
7. Regarding claims 6 and 28, Stevens discloses a primary heart bypass circuit perfusing a coronary blood vessel (column 23, lines 7-23 and embodiment depicted in Fig. 2, coronary arteries 50 and 51).
8. Regarding claims 7 and 29, Stevens a secondary circuit fluidically isolated from a primary heart bypass circuit (column 24, lines 17-26 and Fig 16, blood drawn in through inlets 218 and 219, and saline infused through aperture 221).
9. Regarding claims 8 and 30, Stevens discloses a second circuit continuously perfusing the heart (column 24, lines 17-21 and column 25, lines 17-27). Examiner reads the language "continuously" broadly to include any time period.
10. Regarding claims 9 and 31, Stevens discloses a secondary circuit perfusing a chamber of the heart (column 24, lines 22-26 and Fig. 16, perfusing right atrium 222 with saline).

11. Regarding claims 10 and 32, Stevens discloses a secondary heart bypass circuit perfusing a coronary blood vessel (column 25, lines 1-5, 17-25 and 34-39; Fig. 16, balloon 227 not occluding coronary arteries). The aortic root includes coronary blood vessels.
12. Regarding claims 11 and 33, Stevens discloses receiving pumping medium from the aorta and returning the pumping medium to a vena cava (column 25, lines 17-29; Fig. 21, venting lumen 233 to aorta and column 24, lines 22-26; Fig. 16, saline infused to aperture 221 within vena cava).
13. Regarding claims 18-23 and 40-43, Stevens discloses visualizing with an angioscope, visualizing the heart through a catheter, observing a heart chamber, observing a heart valve and performing an intracardiac procedure (column 25, lines 59-67 through column 26, lines 1-30 and Fig. 8, angioscope 67). Examiner reads the language "endoscope" broadly to include an angioscope.
14. Regarding claim 44, Stevens discloses an apparatus further comprising an intracardiac procedure device (column 25, lines 42-45 and Fig. 17, catheter 212 having instrumentation 237 including a laser).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 16, 17, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US Patent 5,702,368) in view of Loeb (US Patent 4,448,188).

18. Regarding claims 16, 17, 38 and 39, Stevens discloses the invention as substantially claimed. See above. However, Stevens lacks a perfluorocarbon. Loeb discloses a perfluorocarbon (column 2, lines 21-23 and column 5, lines 13-18). A perfluorocarbon is inherently a fluorocarbon. Loeb provides the advantage of visualizing an internal structure while maintaining adequate oxygenation to surrounding tissues (column 1, lines 62-68 through column 2, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stevens as discussed with the perfluorocarbon as taught by Loeb in order to adequately oxygenate surrounding tissues.

Allowable Subject Matter

19. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Machold et al. (US Patent 5,458,574)
- ❖ Stevens et al. (US Patent 6,029,671)
- ❖ Stevens et al. (US Patent 6,955,175)
- ❖ Sarns (US Patent 3,851,646)
- ❖ Suresh et al. (US Patent Application Publication No. 2001/0003795)
- ❖ Starksen et al. (US Patent Application Publication No. 2005/0119523)
- ❖ Morales et al. (US Patent Application Publication No. 2003/0233142)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

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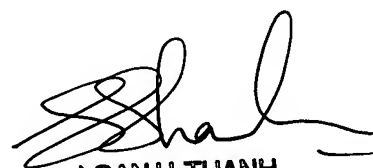
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761

Adam Marcetich

AMM


LOAN H. THANH
PRIMARY EXAMINER